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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,208	11/16/2005	Walter Gumbrecht	0250109	5284

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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,208	GUMBRECHT ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/09/2008*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed May 05, 2008. Claims 1 and 4-6 were amended and claims 2-3 and 16-20 were cancelled. **THIS ACTION IS MADE FINAL.**

2. Claims 1 and 4-15 are pending in this application and are under prosecution.

Amendments to Claims

3. Amendments to the claims 1 and 4-6 have been reviewed and entered.

Drawings

4. Applicants drawings filed on June 20, 2005 are acceptable.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-6, 8-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al (WO 00/62048, published Oct. 19, 2000) in view of Cote et al (USPN 6,485,703 issued Nov. 26, 2002) and further in view of Zhou et al (USPGPUB NO. 2004/0121339 filed Dec. 19, 2002). The WIPO document cited was not published in English. The US equivalent USPN 7,208,077 is deemed an English translation. The content of the WO 00/62048 are deemed to be identical to the USPN 7,208,077, because of the 371 status of the '077 patent.

Regarding claim 1, Albers et al teaches a DNA chip comprising a flat carrier (Fig. 1a, # 1, column 5, lines 37-38), multiple electrodes arranged in an array position (Fig. 1b, electrodes # 3a and 3a', array position # 4, column 9, lines 18-22), catcher molecules incorporated into gels and introduced into compartment between the walls of the electrode for detecting binding events between the catcher molecules and target molecules (Fig. 1d, Electrode # 3a, walls # 8, column 16, lines 5-8). Albers et al also teaches that the electrodes are embedded in a hydrogel (column 16, lines 18), which are hydrophilic as defined by and a preferred hydrophilic reaction layer recited in claim 9 of the instant invention.

Albers et al also teaches that catcher molecules incorporated in to the gel in the volume compartment of the electrode and accessible to both targets and reagents (column 15, lines 21-27 and column 16, lines 5-8), thus teaching that the immobilized

catcher molecules are distributed three- dimensionally. Albers et al teaches that the electrode has a width of 1 micrometer and the spacing of 0.9 micrometer (column 26, lines 35-37) and covered with hydrogel (column 16, line 18), but are silent about the reaction layer thickness range.

Regarding claim 4, Albers et al teaches that the electrode has a width of 1 micrometer and the spacing of 0.9 micrometer (column 26, lines 35-37) and silent about reaction layer thickness.

Regarding claim 5, Albers et al teaches an interdigital electrode arrangement comprising annular ultra microelectrode (Fig. 2b, electrode # 3a) and auxiliary electrode (Fig. 2a, auxiliary electrode – # 3b, column 8, lines 35-65) and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a two-pole microelectrode system.

Regarding claim 6, Albers et al teaches an interdigital electrode arrangement comprising ultra microelectrodes (Fig. 2c, electrodes # 3, 3') and pair of auxiliary electrodes (Fig. 2a, auxiliary electrodes – # 3b, 3c, column 8, lines 35-65), and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a four-pole microelectrode system.

Regarding claim 8, Albers et al teaches that catcher molecules are incorporated into the gel (column 16, line 5) but are silent about covalent binding.

Regarding claim 9, Albers et al teaches that the reaction layer is hydrogel (column 16, lines 14-18).

Regarding claim 11, Albers et al teaches that the electrode arrangement is an interdigital electrode arrangement (Fig. 1, column 7, lines 39-41).

Regarding claim 12, Albers et al teaches an interdigital electrode arrangement comprising annular ultra microelectrode (Fig. 2b, electrode # 3a) and auxiliary electrode (Fig. 2a, auxiliary electrode – # 3b, column 8, lines 35-65) and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a two-pole microelectrode system.

Regarding claim 13, Albers et al teaches an interdigital electrode arrangement comprising ultra microelectrodes (Fig. 2c, electrodes # 3, 3') and pair of auxiliary electrodes (Fig. 2a, auxiliary electrodes – # 3b, 3c, column 8, lines 35-65), and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a four-pole microelectrode system.

Regarding claim 14, Albers et al teaches a DNA chip that includes a planar substrate, i.e., flat carrier (Fig. 1a, # 1, column 5, line 37), which includes a silicon substrate, i.e., semiconductor layer (Fig. 1d, # 1s, column 9, lines 30-31) and an insulating layer connected thereto (Fig. 1d, # 2, column 9, line 30), the insulating layer carrying the electrode arrangement (Fig. 1d, electrodes # 3a and 3a'). Albers et al teaches that catcher molecules incorporated in to the gel in the volume compartment of the electrode (Fig. 1d, side wall # 8, electrode 3 3a, column 15, lines 21-27 and column 16, lines 5-8). Albers et al also teaches that an insulating layer is between the electrode and the semiconductor layer (Fig. 1d, Semiconductor layer # 1s, Insulating layer # 7,

column 10, line 33), thus teaching gel, i.e., reaction layer is remote form the semiconductor layer.

Regarding claim 15, Albers et al teaches in that the semiconductor layer is a silicon layer (Fig. 1d, # 1s, column 9, lines 30-31).

Regarding claims 1 and 4-6, Albers et al teaches hydrogel layer but silent about the reaction layer thickness. However, the size of the reaction layer thickness was known in the art at the time of the claimed invention was made as taught by Cote et al, who teaches thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (Cote et al, column 41, line 54-55).

Albers et al in view of Cote et al do not teach the reaction layer thickness of between 2 and 10 micrometer (limitation of claim 4) or thickness of approximately 3 micrometer (limitation of claim 5) or thickness of approximately 7 micrometer (limitation of claim 6). However, range of thickness of the reaction layer to attach catcher molecules was known at the time of the claimed invention was made as taught by Zhou et al, who teaches bio-microarrays and teaches the polyelectrolyte film, i.e., reaction layer and further teaches the thickness of the polyelectrolyte film ranges from 1 nanometer to 100 micrometers or from 5 nanometers to 20 micrometers or from 50 nanometers to 1micrometer (paragraph 0030), thus providing the thickness recited in said claims. Zhou et al also teaches that the polyelectrolyte film are formed without any synthesis work or special equipment and provide a biologically friendly, solution like environment for biological immobilization of probes and is more sensitive for detecting analytes (Fig. 3, paragraph 0031).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the reaction layer of Albers et al and Cote et al and include polyelectrolyte film of varying thickness of Zhou et al with a reasonable expectation of success.

An artisan would have been motivated to modify the reaction layer of Albers et al and Cote et al and include polyelectrolyte film of varying thickness of Zhou et al with the expected benefit of having a polyelectrolyte film, which does not require any synthesis work or special equipment and provide a biologically friendly, solution like environment for biological immobilization of probes and is more sensitive for detecting analytes as taught by Zhou et al (Fig. 3, paragraph 0031).

Regarding claim 8, Albers et al teaches hydrogel layer but silent about the hydrogel layer containing coupling groups for the covalent binding of catcher molecules. However, the hydrogel layer containing coupling groups for the covalent binding of catcher molecules was known at the time of the claimed invention was made as taught by Cote et al, who teaches that the hydrogel, i.e., a reaction layer contains coupling groups for the covalent binding of catcher molecules (column 7, lines 9-14) and further teaches proper choice of hydrogel enhance the speed and sensitivity of analyte detection (column 10, lines 29-38).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the hydrogel of Albers et al and include the selected hydrogel of Cote et al with a reasonable expectation of success.

An artisan would have been motivated to modify the hydrogel of Albers et al and include the selected hydrogel of Cote et al with the expected benefit of enhancing the speed and sensitivity of analyte detection as taught by cote et al (column 10, lines 29-38).

8. Claims 1, 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al (WO 00/62048, published Oct. 19, 2000) and Cote et al (USPN 6,485,703 issued Nov. 26, 2002) in view of Zhou et al (USPGPUB NO. 2004/0121339 filed Dec. 19, 2002) as applied to claims 1 and 6 above and further in view of Valint et al (USPG PUB NO. 2002/0102415 published Aug. 1, 2002).

This is a new rejection necessitated by claim amendments and dependency.

Claim 10 is dependent from claim 6, which is dependent from claim 1. Claim 7 was dependent from claim 1. Teachings of Albers et al, Cote et al and Zhou et al regarding claims 1 and 6 are described in this office action in section 7.

Regarding claim 7, Cote et al teaches that the thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (column 41, line 54-55). Albers et al, Cote et al and Zhou et al are silent about its thermal stability. However, thermal stability of hydrogel was known in the art at the time of the claimed invention was made as taught by Valint et al who teaches a hydrogel polymer that is resistant to heat up to 90C, i.e., approximately 95C (paragraph 0217). Valint et al further teaches that hydrogel having thermal stability is sterilized easily using conventional autoclave without changes in its property (paragraph 0152, Table 13).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the gel of Albers et al, Cote et al and Zhou et al and include the thermally stable hydrogel of Valint et al with a reasonable expectation of success.

An artisan would have been motivated to modify the gel of Albers et al, Cote et al and Zhou et al and include the thermally stable hydrogel of Valint et al with the expected benefit of sterilizing hydrogel using conventional autoclave, still retaining its property as taught by Valint et al (paragraph 0152).

Regarding claim 10, Albers et al teaches a hydrogel (column 16, lines 14-18). Cote et al teaches hydrogel polymers include PEG monomers (column 18, lines 17-67) or vinyl containing monomers (Cote et al, column 19, lines 29-67) or copolymers containing vinyl and methylacrylamate monomers (column 7, lines 9-12). Albers et al, Cote et al and Zhou et al are silent about hydrogel is an acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups. However, acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups was known at the time of the claimed invention was made as taught by Valint et al who teaches that the hydrogel comprise an acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups (paragraph 0071).

Valint teaches that hydrogel with copolymers, e.g., maleic anhydride and glycidyl methacrylate is advantageous in providing a thicker coating by promoting the aggregation of the hydrophilic polymer, i.e., hydrogel in solution (paragraph 0067).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made modify the hydrogel of Albers et al, Cote et al and Zhou et al and include the hydrogel with copolymers of Valint et al with a reasonable expectation of success.

An artisan would have been motivated to modify the hydrogel of Albers et al, Cote et al and Zhou et al and include the hydrogel with copolymers of Valint et al with the expected benefit of providing a thicker coating by promoting the aggregation of the hydrophilic polymer, i.e., hydrogel in solution as taught by Valint et al (paragraph 0067).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-6, 8-9 and 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/539,817 in view of Cote et al (USPN 6,485,703 issued Nov. 26, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Regarding instant claim 1, claims 1, 8 and 17 of the '817 copending application are drawn to a DNA chip comprising a carrier, a microarray of spots arranged on the carrier, containing immobilized catcher molecules, each spot containing a thin-film four –pole system configured to measuring binding events between the catcher molecule and target analytes. Claims 8-10 and 17of the '817 copending application are further drawn to thin-film microelectrode system embedded in a hydrophilic reaction layer having thicknesses the range of 1L to 5L, L being the sum of electrode width and electrode spacing.

Claims of '817 are not drawn to thickness of the reaction layer. However, Cote et al, teaches the reaction layer thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (column 41, line 54-55) and further teaches proper choice of hydrogel enhances the speed and sensitivity of analyte detection (column 10, lines 29-38).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the selected hydrogel of Cote et al with the expected benefit of enhancing the speed and sensitivity of analyte detection as taught

by cote et al (column 10, lines 29-38). Hence, claims 1-6, 8-9 and 11-15 of the instant application are obvious over claims 1-18 of the '817 copending application in view of Cote et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to remarks from the Applicants

Claim Rejections under 35 U.S.C. § 102(b)

11. Applicant's arguments with respect to claims 1, 9 and 11-15 being anticipated by Albers et al have been considered but are moot in view of the new grounds of rejection (Remarks, pg. 7, paragraph 2). Applicant's argument regarding teachings of Albers et al as it applies to the rejected claims are addressed under 35 U.S.C. § 103(a).

Claim Rejections under 35 U.S.C. § 103(a)

12. Applicant's arguments with respect to teachings of Albers et al in view of Cote et al have been considered but are moot in view of the new grounds of rejection (Remarks, pg. 8, paragraphs 2-4, pg. 9, paragraph 1-2).

Applicant argues that "Catcher molecules of Albers et al are immobilized on a surface, instead of being distributed three dimensionally" (Remarks, pg. 8, paragraph 2). This argument is not persuasive because as described in this office action in section 7, Albers et al teaches that catcher molecules incorporated in to the gel in the volume

compartment of the electrode and specifically teaches "Gels with incorporated affinity-binding molecules" (column 16, line 5). Since the catcher molecules of Albers et al are incorporated in the gel and are in the volume compartment of the electrode, the reference teaches molecules are distributed three-dimensionally as claimed.

Applicant argues that "Albers fails to disclose a thickness for the gel layer" (Remarks, pg. 8, paragraph 3). This argument is moot because, as described in this office action in section 7 in detail, both Cote et al and Zhou et al teaches the claimed range of reaction layer thickness.

Applicant argues that "Albers et al in view of cotes et al fails to teach a hydrophilic reaction layer which is permeable to target molecules and in which immobilized catcher molecules are distributed three-dimensionally, the hydrophilic reaction layer having a thickness approximately in the range of 1L to 5 L, L being the sum of electrode width and electrode spacing" (Remarks, pg. 9, paragraph 2). This argument is not persuasive, because reaction layer thickness range is taught by Zhou et al as described in this office action in section 7.

Double Patenting

13. Applicants have not traversed the above rejections in obviousness-type double patenting. Therefore, provisional obviousness-type double patenting rejection of claims 1-2 and 4-15 over claims 1-18 of copending Application No. 10/540,208 are maintained (Remarks, pg. 10, paragraphs 1-2).

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

Narayan K. Bhat, Ph. D.

/BJ Forman/

Primary Examiner, Art Unit 1634